SEP 1 5 2000

K000515

510(k) SUMMARY

SUBMITTED BY

Prosie Rey-Fessler
Director, Regulatory Affairs & Quality Assurance
Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

Date Submitted: February 14, 1999

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Bone Void Filler
Common/Usual Name:	Bone Void Filler or Bone Graft Substitute
Product Classification:	Unclassified
Proprietary Name:	Pro Osteon® 200R Resorbable Bone Graft Substitute

PREDICATE DEVICE

Interpore Cross International's Pro Osteon 500R Resorbable Bone Graft Substitute [reference 510(k) K980817]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

DEVICE DESCRIPTION AND MATERIALS OF CONSTRUCTION

Pro Osteon 200R Resorbable Bone Graft Substitute is an osteoconductive porous calcium carbonate implant similar in structure to human cancellous bone. It is supplied sterile in various shapes and sizes.

Pro Osteon 200R Resorbable Bone Graft Substitute has a trabecular structure with multidirectional interconnected porosity with an approximate pore diameter of 190 - 230 microns. The product consists of an underlying calcium carbonate matrix covered by a very thin outer layer of calcium phosphate, approximately 2 to 10 microns in thickness. The calcium phosphate is located on the outer surface of the porosity throughout the entire structure of the implant. Once implanted, the calcium phosphate outer layer will slowly resorb, delaying exposure of the underlying and faster

resorbing calcium carbonate.

When Pro Osteon 200R is placed in direct contact with viable bone, the reticulated spaces in the implant are infiltrated with tissue. Bone formation occurs in apposition to the calcium phosphate surface and within the interstices of the implant skeleton. As the implant resorbs, bone and soft tissue grow into the space previously occupied by the calcium carbonate.

INDICATIONS FOR USE

Pro Osteon 200R Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Pro Osteon 200R is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

1. Contraindications

   Pro Osteon 200R is contraindicated for fractures of the growth plate; for segmental defects; for indications which may be subjected to excessive impact or stresses; when there is significant vascular impairment proximal to the graft site; when there are metabolic or systemic disorders that affect bone or wound healing; when stabilization of the fracture is not possible; in cases where intraoperative soft tissue coverage is not planned or possible, and in infected sites.

2. Warnings and Precautions

   Pro Osteon 200R does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure rigid stabilization of the defect in all planes. Pro Osteon 200R Resorbable Bone Graft Substitute is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Complete postoperative wound closure is essential.

   Pro Osteon 200R is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

3. Complications

Potential complications using this device are the same as those encountered in autogenous bone grafting procedures and include the following: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis.

COMPARISON TO THE PREDICATE DEVICE

The Pro Osteon 200R Resorbable Bone Graft Substitute product design, materials of construction or chemical composition, and function as a bone void filler or bone graft substitute are substantially equivalent to the predicate device, Pro Osteon 500R Resorbable Bone Graft Substitute.

TESTING SUMMARY

Results of nonclinical testing, including bench testing and animal studies, support substantial equivalence of Pro Osteon 200R Resorbable Bone Graft Substitute to the predicate device, Pro Osteon 500R Resorbable Bone Graft Substitute.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2000

Ms. Prosie Rey-Fessler
Director, Quality Assurance and Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

Re: K000515
Trade Name: ProOsteon 200R
Regulatory Class: Unclassified
Product Code: MQV
Dated: June 16, 2000
Received: June 19, 2000

Dear Ms. Rey-Fessler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000515

Device Name: Pro Osteon® 200R Resorbable Bone Graft Substitute

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000515

Prescription Use ✓ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

Optional Format 1-2-96)